

§ 522.775 Doxapram.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) doxapram hydrochloride.

(b) *Sponsor.* See Nos. 000010 and 015914 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For intravenous use in dogs and cats at a dose of 2½ to 5 mg per pound (lb) body weight in barbiturate anesthesia, 0.5 mg/lb in inhalation anesthesia; for intravenous use in horses at 0.25 mg/lb body weight in barbiturate anesthesia, 0.2 mg/lb in inhalation anesthesia, 0.25 mg/lb with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(2) *Indications for use.* Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; or to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; or to stimulate respiration following dystocia or caesarean section.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 261, Jan. 4, 2007, as amended at 75 FR 10167, Mar. 5, 2010]

§ 522.778 Doxycycline hyclate.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Apply subgingivally to periodontal pocket(s) of affected teeth.

(ii) *Indications for use.* For treatment and control of periodontal disease.

(iii) *Limitations.* Do not use in dogs less than 1-year old. Use of tetracyclines during tooth development has been associated with perma-

nent discoloration of teeth. Do not use in pregnant bitches. Use in breeding dogs has not been evaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 8349, Feb. 19, 1998, as amended at 65 FR 45878, July 26, 2000]

§ 522.784 Doxylamine succinate injection.

(a) *Specifications.* Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.¹

(3) Not for use in horses intended for food.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.800 Droperidol and fentanyl citrate injection.

(a) *Specifications.* Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

§ 522.810

(2) It is administered as follows:

(i) For analgesia and tranquilization administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 40 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 64 FR 15684, Apr. 1, 1999]

§ 522.810 Embutramide, chloroquine, and lidocaine solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.

(b) *Sponsor.* See No. 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One mL per 5 pounds of body weight.

(2) *Indications for use.* For euthanasia.

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts

21 CFR Ch. I (4–1–12 Edition)

this drug to use by or on the order of a licensed veterinarian.

[70 FR 36337, June 23, 2005]

§ 522.812 Enrofloxacin.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.226 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

(e) *Conditions of use*—(1) *Dogs.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

(ii) *Indications for use.* For the management of diseases associated with bacteria susceptible to enrofloxacin.

(2) *Cattle.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount.* Single-dose therapy: 7.5 to 12.5 mg/kg of body weight by subcutaneous injection. Multiple-day therapy: 2.5 to 5.0 mg/kg of body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) *Indications for use*—(A) *Single-dose therapy:* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle.

(B) *Multiple-day therapy:* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle.

(iii) *Limitations.* Animals intended for human consumption must not be